PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Bruno Guy et al.	Art Unit:	1645
Serial No.:	09/403,967	Examiner:	V. Portner
Filed:	March 28, 2000	Customer No.:	21559
Title:	Anti-Helicobacter Vaccine Composition Comprising a TH1-Type Adjuvant		

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

REPLY TO OFFICE ACTION

In reply to the Office Action that was mailed in connection with the above-captioned application on September 2, 2003, applicants submit the following Amendment and Remarks.

AMENDMENT

Please amend the claims as follows.

1-38. (Canceled).

39. (Three Times Amended) A method of inducing a T helper 1-type immune response against Helicobacter in a patient, said method comprising administering to the patient an immunogenic agent derived from Helicobacter and a compound that promotes induction of a T helper 1-type immune response against Helicobacter, said immunogenic agent being a preparation of inactivated Helicobacter bacteria, a Helicobacter cell lysate, or a Helicobacter polypeptide or peptide in purified form, and said compound being ~~selected from the group consisting of:~~

~~(i) a saponin purified from an extract of *Quillaja saponaria*; and~~

~~(ii)~~ a cationic lipid or a salt thereof, wherein said lipid or salt thereof is a weak inhibitor of protein kinase C and has a structure that comprises a lipophilic group derived from cholesterol, a bonding group selected from carboxyamides and carbamoyls, a spacer arm consisting of a branched or unbranched linear alkyl chain of 1 to 20 carbon atoms, and a cationic amine group selected from primary, secondary, tertiary, and quaternary amines, wherein said lipid or salt thereof is not provided in the form of a liposome.

40-42. (Canceled).

43. (Previously Presented) The method of claim 39, wherein the compound is a cationic lipid made in the form of a dispersion.

44. (Previously Presented) The method of claim 39, wherein the compound is the cationic lipid 3-beta-[N-(N',N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-chol) or a salt thereof.

45. (Canceled).

46. (Previously Presented) The method of claim 39, wherein the T helper 1-type immune response is characterized by a ratio of ELISA IgG2a:IgG1 titres that is greater than or equal to 1:20, when said method is carried out in a mouse, the IgG2a and IgG1 being immunoglobulins induced against Helicobacter.

47. (Previously Presented) The method of claim 46, wherein the T helper 1-type immune response is characterized by a ratio of ELISA IgG2a:IgG1 titres that is greater than or equal to 1:10.

48. (Previously Presented) The method of claim 47, wherein the T helper 1-type immune response is characterized by a ratio of ELISA IgG2a:IgG1 titres that is greater than or equal to 1:2.

49. (Canceled).

50. (Currently Amended) The method of claim 39 ~~49~~, wherein the immunogenic agent derived from Helicobacter comprises the UreB or UreA subunit of Helicobacter urease.

51. (Previously Presented) The method of claim 39, wherein the immunogenic agent derived from Helicobacter is derived from *Helicobacter pylori*.

52. (Previously Presented) The method of claim 39, wherein the immunogenic agent and the compound are administered to the patient by a systemic route.

53. (Previously Presented) The method of claim 52, wherein the systemic route is the strict systemic route.

54. (Previously Presented) The method of claim 52, wherein the immunogenic agent and the compound are administered to the patient by a systemic route in a region of the patient that is situated under its diaphragm.

55. (Previously Presented) The method of claim 52, wherein the immunogenic agent and the compound are administered to the patient by a systemic route in the dorsolumbar region of the patient.

56. (Previously Presented) The method of claim 52, wherein the systemic route is selected from the group consisting of the subcutaneous route, the intramuscular route, and the intradermal route.

57. (Previously Presented) The method of claim 39, wherein the immunogenic agent and the compound are administered to the patient twice or three times by a systemic route during the same treatment.

58. (Canceled).